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EXAMINER

HARTLEY, MICHAEL G

ART UNIT

PAPER NUMBER

1616

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25

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicant No.	Applicant(s)
	09/446,328	SPECK ET AL.
	Examiner	Art Unit
	Michael G. Hartley	1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 10 April 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 18-45 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 18-45 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

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Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/10/2003 has been entered.

Response to Arguments

Any previous rejections that are not reiterated herein have been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 18 is rejected under 35 U.S.C. 102(e) as being anticipated by Galkin (US 5,844,965), for the reasons set forth in the office action mailed 12/31/2001.

Applicant's arguments filed 4/10/2003 have been fully considered but they are not persuasive.

Applicant asserts that while Galkin states the possibility of using contrast agents in mammography, no such imaging was done and Galkin does not name one single contrast agent, let alone, disclose the use of the claimed nonspecific, extracellular or urographic contrast agents in mammography.

This is not found persuasive because Galkin clearly states that mammography has been performed with the use of contrast agents, see column 4, lines 44-56. The patent need not exemplify such a method to clearly disclose that such a method has been performed and is therefore known in the art. Clearly, the disclosure in columns 4-5 teaches the use of contrast agents in x-ray projection mammography. In response to applicant's argument that the references fail to show certain features of

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applicant's invention, it is noted that the features upon which applicant relies (i.e., claimed nonspecific, extracellular or urographic contrast agents) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Claim 18, as rejected by Galkin, only recites "intravenous contrast agent" and not nonspecific, extracellular or urographic as asserted in the arguments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over either one of Galkin (US 5,844,965) in view of Chang (Radiology), Ranney (US 5,260,050), Hilger (US 5,849,259), Brasch (US 6,009,342), Kirpoitin (US 5,411,730) and Platzek (US 6,054,117), for the reasons set forth in the office action mailed 12/31/2001.

Applicant's arguments filed 4/10/2003 have been fully considered but they are not persuasive.

Applicant asserts that Galkin fails to teach even one specific suitable contrast agent that is used in mammography and the secondary references only teach contrast agents without any motivation for their use in mammography.

This is not found persuasive because Galkin provides a general teaching that the contrast of projection (i.e., x-ray) mammography may be improved with the use of known contrast agents and the secondary references teach that various x-ray contrast agents, as claimed, are known in the art for providing increased contrast in imaging, e.g., x-ray imaging. One of ordinary skill in the art would have been motivated to employ a contrast agent that is known to be safe and effective, as taught in the

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secondary references, as the contrast agent generally stated in the methods of Galkin for projection mammography (e.g., x-ray mammography) to gain the benefits of safety and efficacy.

Applicant asserts that Galkin fails to provide an enabling disclosure, since Galkin provides no examples.

This is not found persuasive because examples are not required for an enabling disclosure. Mammography is a well-known and established technique, as is the administration of a contrast agent. By Galkin disclosing that contrast agents may be used to improve imaging in mammography, one of ordinary skill in the art would have had the knowledge to administer the contrast agent and perform mammography given the state of the art. It is noted that the instant application only has a single example of mammography using a single contrast agent. It may be said that if applicant's assertion regarding lack of enabling disclosure for lack of examples were true, the instant application would only be enabled for the contrast agent iopromide, as this is the only contrast agent used in the single example of projection mammography in the present application.

Claims 18-20, 24-29, 32, 36 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over or Nitecki (US 5,756,006), for the reasons set forth in the office action mailed 12/31/2001.

Applicant's arguments filed 4/10/2003 have been fully considered but they are not persuasive.

Applicant asserts that Nitecki teaches mammography among a variety of applications and mentions the use of contrast agents among a variety of possibilities, thus, only teaches such a method in a general sense.

This is not found persuasive because the entire disclosure of Nitecki is related to new and improved contrast agents for methods of X-ray imaging, see abstract and column 1. Nitecki clearly states "Another possible use involves...mammography" in column 2. This is not a large list of possible uses, but rather a very limited number of uses, namely three, for vascular area "as well as use in lymphography and mammography," (column 2, lines 31-35). Clearly, this provides a teaching that the disclosed contrast agents may be used in mammography. Obviousness does not require absolute predictability, *In re O'Farrell*, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988).

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Applicant asserts that Nitecki fails to provide an enabling disclosure, since Nitecki provides no examples.

This is not found persuasive because examples are not required for an enabling disclosure.

Mammography is a well-known and established technique, as is the administration of a contrast agent. By Nitecki disclosing improved contrast agents which are useful for mammography, one of ordinary skill in the art would have been able to employ the well established administration of such contrast agent as disclosed by Nitecki to the well established procedure of x-ray (or projection) mammography. It is noted that the instant application only has a single example of mammography using a single contrast agent. It may be said that if applicant's assertion regarding lack of enabling disclosure for lack of examples were true, the instant application would only be enabled for the contrast agent iopromide, as used in the single example.

In sum, one of ordinary skill in the art would have been motivated to employ the new contrast agents disclosed by Nitecki for all that Nitecki teaches that they are useful for, including mammography to obtain the benefits of the contrast agent in improving the imaging.

It is noted that this rejection over Nitecki for the present claims that employ contrast agents that are not within the scope of those taught or suggested by Nitecki, has been withdrawn (e.g., non-peptide contrast agents, etc.).

The declaration under 37 CFR 1.132 filed 2/10/2003 is insufficient to overcome the rejection of claims 18-45 based upon 35 USC 102 or 103, as set forth in the last Office action (reiterated above) because: this declaration by Bernd Hamm opines that mammography has not been performed with the use of contrast agents prior to 1999. However, since the prior art clearly provides such a teaching, in a published patent, such a method is disclosed in the prior art and this declaration cannot be used to overcome the teaching in the prior art. The opinion that such a method has not been performed fails to contradict the teaching of such a method in the prior art.

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Conclusion

No claims are allowed at this time.

This is a RCE of applicant's earlier Application No. 09/446,328. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose G. Dees can be reached on (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Michael G. Hartley
Primary Examiner
Art Unit 1616

MH
May 23, 2003